

Remarks

Claims 1 –10 were presented for examination in the present application. The instant amendment cancels claims 2 and 4 and adds new claims 11-14. Thus, claims 1, 3 and 5-14 are presented for consideration upon entry of the instant amendment.

Claims 1-10 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-22 of U.S. Application No. 10/561,751 in view of U.S. Patent No. 5,254,348 to Hoffman et al. In response, Applicants are submitting a terminal disclaimer to obviate this rejection. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

Independent claim 1, as well as dependent claims 2-5 and 10, are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,254,348 to Hoffman et al. (hereinafter "Hoffman") and U.S. Patent No. 5,518,212 to Spada et al. (hereinafter "Spada"). Applicants respectfully traverse this rejection for the reasons below. Claims 2 and 4 have been canceled, therefore this rejection is moot.

Claim 1 now provides for a tulobuterol adhesive patch including, inter alia, (a) a support, (b) a pressure-sensitive adhesive layer and (c) a release liner laminated in that order, wherein the pressure-sensitive adhesive layer contains a plasticizer, tulobuterol as a percutaneous absorbing agent and the pressure-sensitive adhesive agent is an acrylic-based pressure-sensitive adhesive agent which is a copolymer of an acetoacetoxyalkyl (meth)acrylate and one or more vinyl monomers that are copolymerizable with the acetoacetoxyalkyl (meth)acrylate, wherein the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate.

Hoffman provides for a tulobuterol patch for the treatment of bronchial asthma having a backing layer, an active substance and a matrix layer containing a styrene-butadiene-styrene- or styrene-isoprene-styrene block copolymer. Hoffman fails to

disclose or suggest the use of a copolymer of an acetoacetoxyalkyl (meth)acrylate and a vinyl monomer, wherein the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate, as recited in claim 1.

Spada provides for a pressure-sensitive adhesive possessing improved cohesive strength without significant, if any, loss of adhesion or tack. However, Spada also fails to disclose or suggest a vinyl monomer containing diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate, as recited in claim 1. It is essential for the pressure sensitive adhesive polymer of the present application to contain diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate in order to improve the characteristics of the copolymer to be suitable for use as a medical patch. Thus, Spada fails to overcome the deficiencies of Hoffman.

Furthermore, Spada fails to disclose the use of a copolymer of acetoacetoxyalkyl (meth)acrylates and vinyl monomer in a medical patch, as described in the present application. In contrast, Spada provides in column 10 lines, 22-37:

"the described pressure sensitive adhesives can be applied to any backing which it is desired to adhere to another surface or article. Illustrative backings include flexible and rigid (solid) natural and synthetic materials such as plastics, elastomers, solid metals and foils, ceramics (tiles, glass, etc.), wood, papers and cardboard, leather materials, etc. of essentially any form including films, solid articles, woven and non-woven textile materials, etc. illustrative uses of such articles include wall coverings (paper, fabric, films, etc.), upholstery items, construction roofing and siding materials, tapes of all varieties (including those having backings comprised of woven or non-woven fabrics, paper, polymeric films, metal foils, foams, etc., including double faced tapes and so called transfer tapes), packaging, floor and wall tile and other floor and wall coverings, paneling, etc."

Spada does not suggest a patch that is to be applied to the skin, nor one that is to be peeled off once applied. Instead, it is understood from the above description that Spada illustrates the use of a pressure sensitive adhesive requiring strong adhesion and anti-exfoliation. The strong adhesion of pressure sensitive adhesive polymers to

plastics, ceramics, such as tiles and glass, and wood is completely different from the adhesion of a medical patch applied to the skin as described in the present application.

In general, when a pressure sensitive adhesive polymer is used as a base material of a medical patch it is necessary that: the medicine is dissolved in the polymer at a suitable concentration, the medicine is released to the skin, the polymer provides no skin irritation and the polymer satisfies various adhesive properties such as cohesive force, pressure-sensitive adhesive force and autohesion. Autohesion is the ease of separating two patches when they adhere to each other on the adhesive surfaces. This is an important factor to consider when a patch is applied on skin. However, autohesion is not considered when a pressure sensitive adhesive strongly attaches to the surface of plastics and ceramics, as described in Spada.

Another important factor is the release of medicine from the adhesive layer to the skin, and its subsequent absorption by the skin, since it demonstrates the medicinal effect of the patch. In contrast, this factor is not relevant or considered in Spada, therefore it has not been disclosed. Furthermore, when developing a medical patch it is necessary that the medicine dissolves in the polymer at a suitable concentration, that there is no irritation to skin, that patch remains attached to the skin for an extended time in spite of perspiration and that the patch can be removed without serious stimulation to skin. Again, the patch of Spada does not require consideration of these factors, therefore they were not disclosed.

Finally, as described in the examples of the present application, the patch utilizing acetoacetoxyalkyl (meth)acrylate and vinyl monomer is superior in all aspects than commercially available tulobuterol patches utilizing: 1) non-aqueous acrylic pressure sensitive adhesives (Comparative Example 1 and 2), 2) synthetic gum type pressure sensitive adhesives (Comparative Example 3) and 3) acrylic pressure sensitive adhesives produced by 2-ethylhexyl acrylate and the like (Comparative Example 4). Furthermore, Table 4 illustrates the superiority of the pressure sensitive adhesion polymer of the present application in the features of cohesive force, pressure

sensitive adhesive force and autohesion. Table 1 and Table 2 show that tulobuterol adhesive patch of the present application is superior in the release of tulobuterol and percutaneous permeability compared with patches used in the comparative samples. And Table 3 shows that the patch of the present application does not irritate the skin. As a result, the patch of the present application, utilizing a copolymer of acetoacetoxyalkyl (meta)acrylate and vinyl monomer, achieves a remarkable effect compared to a conventional patch. This is not disclosed in either Hoffman or Spada.

Accordingly, Applicants respectfully submit that Hoffman and Spada, alone or in combination, fail to disclose or suggest independent claim 1. Therefore, claim 1, as well as dependent claims 3, 5 and 10, are in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1, 3, 5 and 10.

Dependent claims 6-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hoffman and Spada as applied to claims 1-5 and 10, and further in view of U.S. Patent No. 5,948,433 to Burton et al. (hereinafter "Burton"). Applicants respectfully traverse this rejection for the reasons below.

Hoffman and Spada are described above. Burton was cited as teaching the use of isopropyl myristate as a plasticizer in a transdermal patch with a pressure sensitive adhesive. The addition of isopropyl myristate as a plasticizer as provided for in Burton to the adhesive of Hoffman and Spada does not provide for the tulobuterol adhesive patch as described in claim 1. Thus, the combination as suggested in the Office Action does not overcome the deficiencies of both Hoffman and Spada.

Therefore, for at least the reasons described above and those provided for independent claim 1, dependent claims 6-8 are patentable over Hoffman and Spada alone or in combination with Burton. Thus, dependent claims 6-8 are in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 6-8.

Dependent claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Hoffman and Spada as applied to claims 1-5 and 10, and further in view of U.S. Patent No. 5,866,157 to Higo et al. (hereinafter "Higo"). Applicants respectfully traverse this rejection for the reasons below.

Hoffman and Spada are described above. Higo was cited as teaching that a physiological active substance may be formulated in an amount from 0.1 to 20% (w/w) based on the total amount of the composition of the adhesive layer. The addition of the amount of active as provided for in Higo to the adhesive of Hoffman and Spada does not provide for the tulobuterol adhesive patch as described in claim 1. Thus, the combination as suggested in the Office Action does not overcome the deficiencies of both Hoffman and Spada.

Thus, for at least the reasons described above and those provided for independent claim 1, dependent claim 9 is patentable over Hoffman and Spada alone or in combination with Higo. Therefore, dependent claim 9 is in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 9.

Claims 11-14, which depend from independent claim 1, have been added to point out various aspects of the present application. It is believed that new claims 11-14 are in condition for allowance. Applicants respectfully submit that the cited art, alone or in combination fails to disclose or suggest the features as recited in claims 11-14.

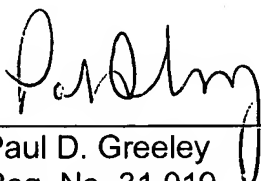
In view of the foregoing, Applicants respectfully submit that all claims present in this application patentably distinguish over the cited prior art and cited combinations of the same. Accordingly, Applicants respectfully request favorable reconsideration and withdrawal of the rejections of the claims. Also, Applicants respectfully request that this application be passed to allowance.

If for any reason the Examiner feels that consultation with Applicants' attorney

would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

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